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9/18/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent

In re patent application of: HOOK, et al

Serial No.: 09/813,820

Examiner: Ford, Vanessa L.

Filed: March 22, 2001

Art Unit: 1645

For: COLLAGEN BINDING PROTEIN COMPOSITIONS
AND METHODS OF USE

Docket #: P06357US02/BAS

DECLARATION UNDER 37 C.F.R. §§ 1.131 AND 1.132
OF DR. JOSEPH M. PATTI, PH.D.

I, Dr. Joseph M. Patti, Ph.D., declare that:

1. I am one of the inventors of the above-identified application, and am well familiar with the subject matter therein and its development. I am currently the Vice President for Preclinical Research for Inhibitex, Inc. a company that specializes in research and development of antibodies to bacterial adhesins such as the collagen binding protein from *Staphylococcus aureus*, and I have also been an inventor or author on numerous patents and articles in this field, including the parent application to the present case which has now issued as U.S. Patent No. 6,288,214.

2. I have now reviewed the prior art cited by the Examiner, and with regard to the Patti et al. 1995 article in the *The Journal of Biological Chemistry*, Vol. 27, No. 20, published May 19, 1995, and this work does not reflect work of another inventive entity, but instead reflects work of the present inventive entity, namely myself, Karen House-Pompeo, and Dr. Magnus Hook. Indeed, this article reflects work that was conceived by the present inventive group, and the other named authors in the article were individuals who carried out experimental work in conjunction with the present invention under our direction and control, and who did not contribute to the invention as reflected in the present claims to the above-identified application.

3. In addition, I have reviewed the other references cited by the Examiner in the above-identified case, and it is clear that these references have no relevance whatsoever to the present invention. The present claims relate to an antibody that was raised to a specific peptide from a subregion of the collagen binding domain from *Staphylococcus aureus*, and this antibody is indeed materially different from antibodies raised against the whole *cna* protein from *Staphylococcus aureus*. This fact was recognized in the parent application to the present case, now U.S. Patent 6,288,214, which related to antibodies to another specific peptide region from the collagen binding domain from *S. aureus*, and not to an antibody generated against the whole *cna* protein which has different properties than one generated against a specific subregion. Accordingly, antibodies that may have been raised previously to the whole CNA protein do not disclose or suggest in any manner the antibodies of the present claims which are raised against the specific region as set forth in SEQ ID NO: 4 of the present application.

4. The other prior art references cited by the Examiner, namely the Wirl et al article and the Ogle et al. article, are even less relevant because they do not even relate to prokaryotic organisms such as bacteria, but instead relate to eukaryotic animals. Specifically, the Wirl et al. article relates to collagen binding proteins from a rat, and Ogle et al. relates to collagen binding proteins from a chicken. Because the collagen binding proteins from these animals are completely different than the collagen binding proteins from the bacteria *S. aureus*, and have materially different structure and function, they could not be used in any manner to generate antibodies to treat or prevent infection as is the case in the present invention, and thus these articles are totally irrelevant to the present claims.

I hereby declare that all my statements made herein are of my own knowledge and are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under 18 U.S.C. § 1001 and that such willful statements made could affect the validity of the application and any patent issued thereon.

9/9/02

Date

Joseph M. Patti

Dr. Joseph M. Patti, Ph.D.